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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,081	03/22/2004	Thaddeus S. Franczyk II	3483 (PHA 4152.5)	1373
26648 7590 06/14/2007 PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006			EXAMINER BADIO, BARBARA P	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			06/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/806,081

Applicant(s)

FRANCZYK ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 51-90 and 194-201 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 88, 194 and 195 is/are allowed.
- 6) ☒ Claim(s) 51-87, 89, 90 and 196-201 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/28/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

**First Office Action on the Merits**

***Specification***

1. The disclosure is objected to because of the following informalities: The structures of formulae D102 and D103 are incorrect because of the number of bonds at C-17 of the steroid ring system.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 51-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite a process for the preparation of compounds of formula 2503 utilizing compounds of formula 2502. However, formula 2503 as defined by the instant claims differ from that set forth in the present specification and, thus, the claimed process differs from that disclosed by the present specification (see pages 6-8, Schemes I-VII on pages 134-140 and Examples 5-7 of the present specification).

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 51-87, 89, 90 and 196-201 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

Claim 51

- recites the phrase, "Y<sup>2</sup> represents hydroxyl alkoxy or O". The substituent "O" is incomplete and, thus, it is unclear what is intended.
- defines but does not identify the variable "R<sup>5</sup>".
- recites R<sup>71</sup> comprises "=CH(OH), =CH(OR<sup>72</sup>) or =CH=O". The variable "R<sup>72</sup>" is not defined and the carbon atoms of the defined groups have too many bonds (Note: R<sup>71</sup> is within a ring system).
- Lacks a period at the end of the claim.

Claim 52

- recites the formula 2503 but does not define said in the instant claim and, therefore, said formula is not defined "above". It is suggested that the phrase "as defined above in Formula 2503" be rewritten as "as defined for Formula 2503 in claim 51" or "as defined in claim 51 for Formula 2503".

Claims 53, 56, 58, 60, 62, 85 and 86

- recite but do not define said "compound of Formula 2501" in the instant claims or parent claim 51. Therefore, the instant claims lack antecedent basis.

Claim 75

- recites the phrase "wherein the ligand comprises phosphorus". Parent claim 71 lacks recitation of a ligand and, thus, the instant claim lacks antecedent basis for the above-mentioned phrase.

Claims 79 and 80

- recite "said intermediate of Formula 2502". Parent claim 51 recites Formula 2502 but lacks reference to said as an "intermediate" and, thus, the instant claims lack antecedent basis for the above-mentioned phrase.

Claims 85 and 86

- refer to the solubility of compound and/or the crystallization of the compound of Formula 2501. Parent claim 83 lacks recitation of compounds of formula 2501 but recites compounds of formulae 2502 and 2503. Therefore, the claimed invention(s) encompassed by the instant claims is unclear.

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Claim 89

- identifies but does not define variables  $R^{17c}$  and  $R^{17d}$ .
- defines but does not identify variables  $R^{17a}$  and  $R^{17b}$ .

Claim 196

- defines but does not identify variable  $R^7$ .
- recites but does not identify/define Formula 1002 in the instant claim and, therefore, said formula is not defined "above".
- formula 1003 as defined by the instant claim is identical to formula 1002 recited by claim 195 and, thus, the claimed invention is unclear.

Claim 197

- defines but does not identify variable  $R^7$ .
- recites but does not identify/define Formula 1003 in the instant claim and, therefore, said formula is not defined "above".
- formula 1004 as defined by the instant claim is identical to formulae 1002 and 1003 recited by claims 195 and 196, respectively, and thus, the claimed invention is unclear.

Claim 198

- defines but does not identify variables  $R^7$  and  $R^{71}$ .

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- recites but does not identify/define Formula 1004 in the instant claim and, therefore, said formula is not defined "above".
- formula 1005 as defined by the instant claim is identical to formulae 1002, 1003 and 1004 recited by claims 195-197, respectively and, thus, the claimed invention is unclear.

Claim 199

- recites but does not identify/define Formula 1005 in the instant claim and, therefore, said formula is not defined "above".

Claim 200

- recites but does not identify/define Formula 1001 in the instant claim and, therefore, said formula is not defined "above".

Claim 201

- recites but does not identify/define Formula 1000 in the instant claim and, therefore, said formula is not defined "above".


***Telephone Inquiry***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
June 11, 2007